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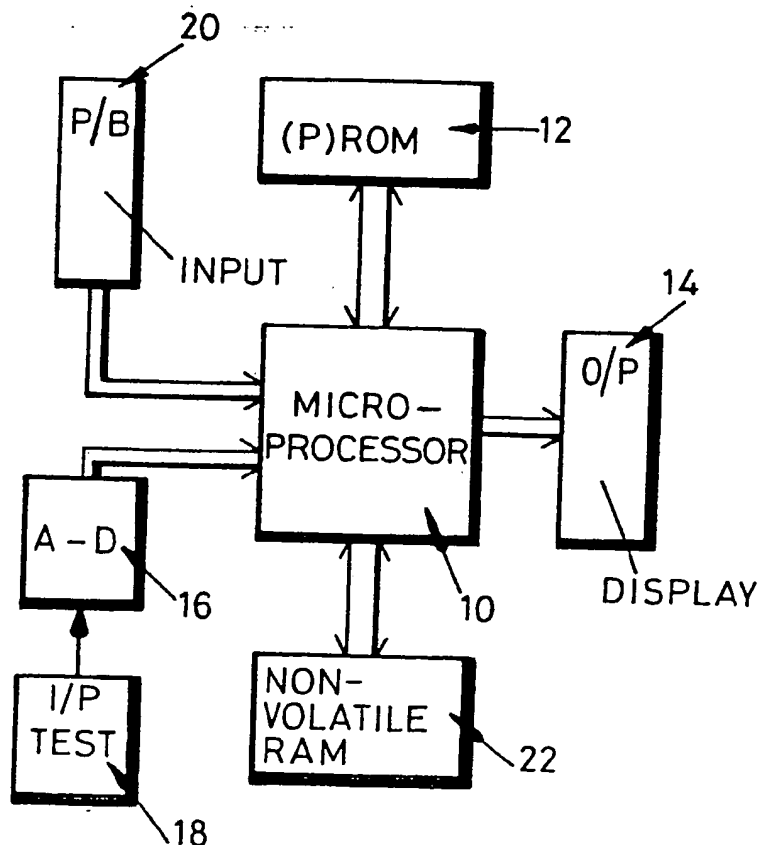
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(58) Field of search

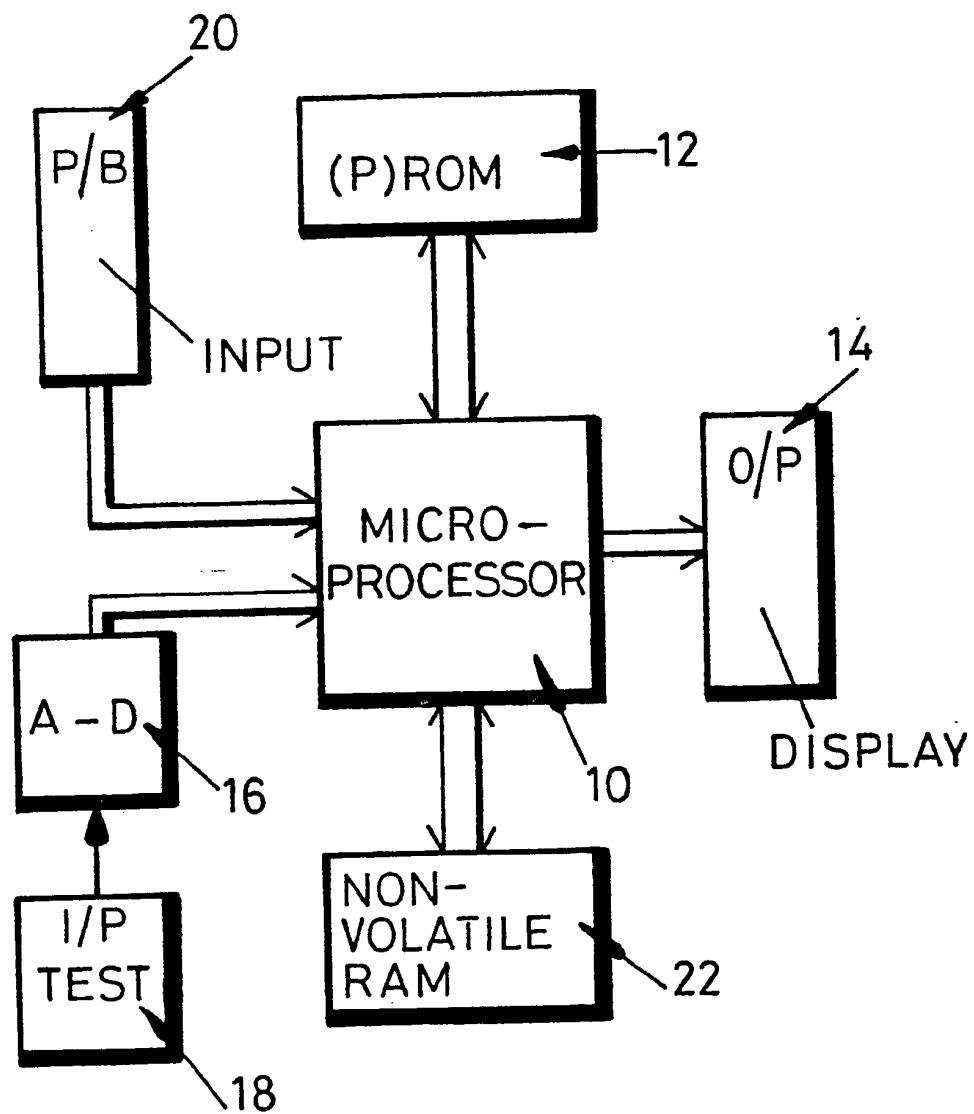
G1A

(54) Test monitor

(57) Microprocessor-controlled electronic monitoring apparatus comprising means for sensing conditions of a test to be monitored, such as blood glucose tests comprises a microprocessor (10), means (12) for storing control information and instructions for the microprocessor to compare test-dependent input signals (via 18, 16) against control information and produce test result signals, and means (14) for presenting those test result signals in a manner intelligible to the user. A further store (22) is provided for information signals input (via 20) the apparatus in connection with specific test monitoring operations by the user, and the first-mentioned means (12) for storing further includes instructions for use by the microprocessor of such input information signals.



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SPECIFICATION

Test monitor

- 5 The invention is described specifically in relation to monitor-type equipment for making medical-type tests, actually for blood glucose level, but is believed to have more general application to portable or occasionally used equipment of a micro-electric nature utilising a microprocessor for control purposes and wherein certain parameters are preset at production or otherwise prior to end-use, and where there may be advantage in or need for the end-user being able to modify same and/or save on subsidiary set-up or conditioning procedures that would obtain for the user for at least some period of time and number of uses of the equipment and/or reduce any requirement for record keeping. In general, of course, such parameters or other information result from end-use and are of more than purely transient or "one-off" value.

- In the above-mentioned specific application to blood glucose monitoring, primary concern is with equipment for home use by patients, typically diabetics, using so-called "dry strip" techniques. Such strips sensitised for response to application of a small blood sample, say from a finger-prick, in a manner detectable by optically, usually by reflection from the strip in a suitable sensor station, are available from different sources with different characteristics, e.g. from Boehringer Mannheim and Ames. The specific equipment of immediate interest can cope with such different strips, but, further and importantly, also with variations from batch to batch of strips from the same source in order to achieve and maintain good accuracy. In practice, a calibration procedure is provided using test strips of known characteristics and it would be useful to be able to avoid recalibration at each equipment use, at least for strips from the same batch. There is also an ever-present desirability for the user to keep and consult a record of previous results of using the monitor.

- According to this invention there is provided microprocessor-controlled electronic monitoring apparatus comprising means for sensing conditions of a test to be monitored and providing input signals for the microprocessor, means for storing control information and instructions for the microprocessor to compare said input signals against said control information and produce test result signals and means for presenting those test result signals in a manner intelligible to the user, wherein a further store is provided for information signals input the apparatus in connection with specific test monitoring operations by the user, and the first-mentioned means for storing further includes instructions for use by the microprocessor of such input information

signals.

- Thus, in preferred embodiments of this invention, provision is made for so-called non-volatile storage of user-originating information, i.e. separately from the basic micro-electric components usually comprising a microprocessor a program-and-parameter store of permanent type (PROM or ROM), input, control and display or other output means, all interconnected with the microprocessor for appropriate entry and use of the contents of the non-volatile storage, usually under control of some extended capability installed in the basic program-and-parameter store.

- In effect, in terms of contemporary developments in micro-electronics, such provision can be achieved readily using a single additional circuit unit or chip of the now-available non-volatile RAM type, or even low-power RAM, e.g. of CMOS type, backed by a small battery, i.e. effectively non-volatile. Any necessary additional control entry means, such as push-button or other pressure- or skin-sensitive switches or further-level operation of existing entry means, is, of course, readily provided.

- It is particularly advantageous to incorporate into a microprocessor-based blood glucose monitor hereof just such a non-volatile store affording retention and use of data comprising user-originating calibration parameters and results of the last *n* readings of the monitor, if not also modifiers or replacements for basic parameters.

- The basic parameters of blood glucose monitors of this invention concern response time of the strip (actually longer for Boehringer Mannheim's than for Ames's) and the actual level of response as seen by the optical system at the strip station. The preferred monitor has count-down facilities to indicate the response time, actually giving audible indication of expiry, i.e. when it is appropriate to take a reading, typically at insertion and then after wiping the strip.

- A system hereof is, in fact, shown in block diagram outline format in the accompanying drawings. There, a microprocessor chip 10 will be connected on a printed circuit board with a permanent program-and-basic parameter store 12 (PROM or ROM), a display 14 of LED or LCD type (typically 3-digits), an analog-to-digital converter 16 fed from an optical strip-sensing station 18 (typically of reflection measuring type), an operator-actuable control input key pad 20 (typically three push-buttons), and, specifically for the purposes of this invention, an effectively non-volatile RAM chip 22.

- It is practical for the read-only store 12 to have control programs and parameters in the form of a basic correlation or function-law between reflection signal levels and corresponding glucose level and relative to "nominal" calibration results (typically for high and low levels at test strips), and a correction

algorithm in relation to "actual" calibration results in relation to how they differ from "nominal". Hitherto the "actual" calibration results and the "real" test results would have resided only in the microprocessor 10. Now, however, they can be written to the non-volatile store 22, say (for the "real" test results) on an automatic "stack" type basis (to hold last n readings), controlled by further "housekeeping" program routines of the store 12, i.e. additional to normally-resident timing, display control, equipment set-up, calibration, etc. routines.

It will thus be evident that the last-made calibration results can be held and used automatically, and that a diary of the last n readings can be held and called up for sequential display as desired. Moreover, it should be further evident that input means could even be provided, or serve, for entering alternatives to the basic correlation or function-law, which could lead to much-enhanced versatility of our monitor additional to greater ease of user-operation.

Having thus described the drawing, and now returning to the aforementioned basic parameters including correlations, it is believed that suitable dry strips will allow application to other than human blood glucose monitoring for diabetics, for example to measure glucose levels in milk, water or vegetables, to monitor animals for some glucose-level affecting condition like pregnancy, even to monitor such things as haemoglobin, etc. in connection with portable medical laboratory equipment of particular application and interest in the so-called third world.

CLAIMS

1. Microprocessor-controlled electronic monitoring apparatus comprising means for sensing conditions of a test to be monitored and providing input signals for the microprocessor, means for storing control information and instructions for the microprocessor to compare said input signals against said control information and produce test result signals and means for presenting those test result signals in a manner intelligible to the user, wherein a further store is provided for information signals input the apparatus in connection with specific test monitoring operations by the user, and the first-mentioned means for storing further includes instructions for use by the microprocessor of such input information signals.

2. Microprocessor-controlled electronic monitoring apparatus according to claim 1 comprising user-operable means for inputting control and/or information signals including said input information signals.

3. Microprocessor-controlled electronic monitoring apparatus according to claim 1 or claim 2, wherein the means for presenting comprises visual display means controlled by

the microprocessor automatically and/or at user command.

4. Microprocessor-controlled electronic monitoring apparatus according to any preceding claim, wherein the input information signals include selected prior result signals.

5. Microprocessor-controlled electronic monitoring apparatus according to claim 4, wherein said selected prior result signals are for the last n operations of the apparatus.

6. Microprocessor-controlled electronic monitoring apparatus according to any preceding claim, wherein the first-mentioned means for storing comprises a semi-conductor memory device of read-only type and the further means for storing comprises a semi-conductor memory device of effectively non-volatile writable type.

7. Microprocessor-controlled electronic monitoring apparatus according to any preceding claim constituting a blood glucose monitor using strips sensitised for response to small blood samples with such response optically sensible by said means for sensing and the further means for storing includes at least user-input designation of type of strip used and results from a test strip for calibration purposes.

8. Microprocessor-controlled electronic monitoring apparatus substantially as herein described with reference to and as shown in the accompanying drawing.

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